Department Of Health And Human Services

Food And Drug Administration

Center For Food Safety and Applied Nutrition Year 2000 Business Continuity And Contingency Plan

November 24, 1999

PREFACE

This Business Continuity and Contingency Plan (BCCP) was prepared by TRW, Inc., for the Food and Drug Administration's (FDA's) Center for Food Safety and Applied Nutrition (CFSAN) under the direction of CFSAN and the Office of Information Resources Management (OIRM). The plan describes the strategic contingencies recommended for the CFSAN's core business process, Premarket Approval, as well as the specific, tested contingency actions to be taken by CFSAN personnel should a Year 2000 problem arise. Also included is a Day One Preparation Checklist to assist CFSAN in preparing for the potential implementation of this plan.

This BCCP should be updated by CFSAN should any changes occur in core business processes, mission critical systems, or contingency actions prior to January 1, 2000. It is also recommended that all personnel involved in the CFSAN's core business processes be made aware of this plan including the contingency actions and supporting materials they will be required to use should a Year 2000 problem arise.

TABLE OF CONTENTS

PAGE

TABLE OF CONTENTS (continued)

PAGE

LIST OF FIGURES

LIST OF TABLES

1. INTRODUCTION

1.1 Overview

One of today's most pressing business concerns is the Year 2000 (Y2K) problem. The Food and Drug Administration (FDA) is working hard to ensure that its automated systems will work properly as we cross into the Year 2000. FDA also realize, however, that no matter how aggressively it works to mitigate risks surrounding the millennium date change, the possibility of system failure exists. The US Office of Management and Budget (OMB) requires all Federal Agencies to develop business continuity contingency plans for critical systems.

The FDA divided its business continuity and contingency planning process into three steps, as described in the "FDA Strategic Business Continuity and Contingency Plan," dated August 1998. The first step was to examine the impact of possible Y2K failures on the Agency's ability to conduct its core business processes and to document this in Business Impact Analysis (BIA) reports. The second step was to prepare BCCPs, based on the business impact analyses, to address the most likely Y2K failure scenarios through the development of contingency strategies. The third and final step was to refine these BCCPs by transforming the contingency strategies into specific contingency actions that would be executed by individuals at their desks, and to test those contingency actions to ensure that the Agency's critical business processes would continue despite any Y2K failures.

This document presents the continuity contingency planning strategies resulting from the business impact analysis performed for the Center for Food Safety and Applied Nutrition (CFSAN) core business process. After FDA approval, it was used to develop the required contingency procedures and training material for performing the various activities in each core business process, in the event of any Y2K failures. This contingency plan addresses only those core business processes supported by a mission-critical automated system.

1.2 Objective

The objective of this plan is to ensure core business processes can continue in the event of a full or partial failure of supporting mission critical systems, whether caused by internal or external factors associated with a Y2K problem. To support this objective, this plan describes an overall contingency strategy and presents specific, tested contingency actions that can be used by CFSAN personnel to continue core business processes.

1.3 Scope

The scope of this document is limited to the business process dependent upon the Food Additives Regulatory Management (FARM) mission-critical system. The following pages present the core process description, supporting mission-critical system description, and potential Y2K failure scenarios documented in the center's BIA document.

1.4 Affected Program Area / Business Process(es)

The core process identified as mission critical, and thus examined, is the Premarket Approval Review. This core business process is related to CFSAN's overall business process to conduct product review and approval on products within the food supply as shown in Figure 1-1.

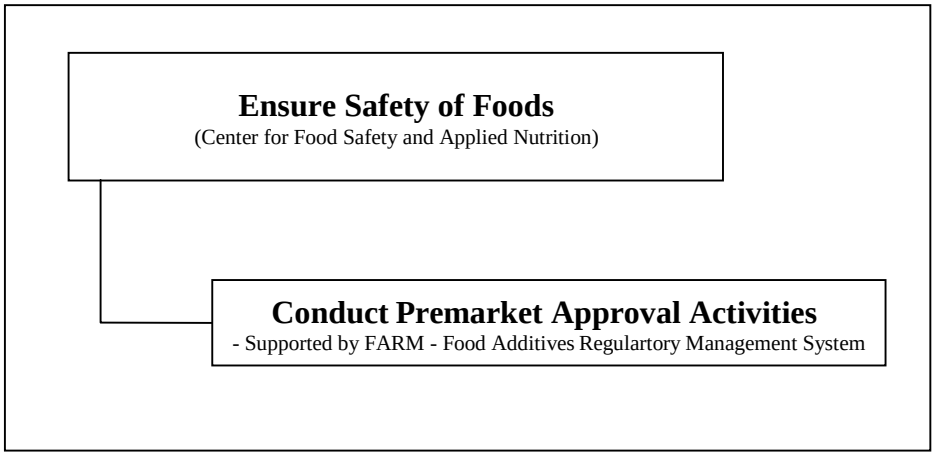

Figure 1-1. CFSAN Business Process Included in Analysis

1.5 Approach

This BCCP was developed based on a two-part approach: first, the development of a contingency strategy, and second, development and testing of specific contingency actions.

For the development of the contingency strategy, each CFSAN mission critical business process was examined at a high level to determine where and how the process depended upon mission-critical systems. The next step was to examine likely Y2K failure scenarios that could affect every aspect of the core business process. Examples of failure scenarios included the failure of the entire system, of interfaces, of external systems, of FDA technical infrastructure components, and of the public utility sector. The severity of the impact of each failure and risk of each failure for a given system or its interfaces were established based on the criteria shown in, Table 1-1 trigger dates and events were developed, and alternative contingency strategies assessed. In accordance with Government Accounting Office (GAO) guidelines, three alternative contingency strategies were considered: manual, semi-automated, and complete automated back-up. Based on the assessment, a single contingency strategy was recommended.

Table 1-1. Impact Severity and Risk Criteria

Element	Level	Description
Severity	High	Impact severely hinders overall business process.
	Medium	Impact hinders overall business process.
	Low	Impact strains organization's ability to complete some portion of the overall business process.
Risk	High	System has not been validated Y2K compliant, no system level contingency plans exist, and no relevant information is available.
	Medium	System has not been validated as Y2K compliant but contingency plans are in place.
	Low	System has been validated as Y2K compliant and contingency plans are in place.

For the development and testing of specific contingency actions, each high-level mission critical business process examined was refined to the level of individual process steps. Each step was analyzed for its dependence on mission critical automated systems and alternative, step-level contingency actions were developed assuming the system would not be available. A list of items required to be in place on January 1, 2000 ("Day One") to support these contingency actions, such as data dumps, screen prints, tracking forms, etc., was captured to support Day One preparation activity. A test of these contingency actions was performed by the actual CFSAN personnel participating in the core business process. The resulting, tested contingency actions are contained in this BCCP for use should a Y2K problem arise. In support of this second phase, a Test Plan, set of Test Cases, and Test Report were prepared for each core business process tested.

1.6 Document Organization

This document is organized into three sections and a set of Appendices.

Section 1 – Introduction: provides the overview, objective, scope, and approach to this planning activity.

Section 2 – Contingency Strategies for CFSAN Business Process Continuity: presents the analysis for CFSAN's core business process supporting the development of the recommended contingency strategy.

Section 3 – Contingency Actions for CFSAN Business Process Continuity: contains a Day One Preparation Checklist, a set of contingency actions at the process step level, and a list of backlog recovery and resolution actions.

Appendices – Contingency Test Materials for CFSAN Business Process Continuity: presents the Test Plan, Test Cases, and Test Reports for CFSAN's core business process.

1.7 Responsibility

The Business Continuity Contingency Plans for CFSAN's core process will be approved and implemented by the designated Center Director/Manager with oversight responsibility.

2. CONTINGENCY STATEGIES FOR CFSAN BUSINESS PROCESS CONTINUITY

Contingency Strategies for CFSAN's Business Process Continuity, presents the analysis for CFSAN's core business processes supporting the development of the recommended contingency strategy.

2.1 Premarket Approval Process

2.1.1 Process Description for Premarket Approval

The mission of the Center for Food Safety and Applied Nutrition (CFSAN) is threefold: (1) to promote and protect the public's health and economic interest by ensuring that the food supply is microbiologically, chemically, nutritionally, and toxicologically safe and wholesome; (2) to ensure that cosmetics are safe; and (3) to ensure that food and cosmetic products are labeled honestly and accurately. The goal for CFSAN's Premarket Approval Process is to streamline the premarket evaluation system for food and color additives, while maintaining the quality and credibility of the review and color certification processes.

Premarket approval of food and color additives is based on the Food Additives Amendment of 1958 to the Food, Drug and Cosmetics (FD&C) Act. The Amendment requires the premarket approval of food ingredients whose safety is not generally recognized or whose regulatory status was not sanctioned by the FDA or the U.S. Department of Agriculture (USDA) prior to 1958. The Color Additives Amendment of 1960 requires premarket approval of color additives in foods, drugs, cosmetics, and some devices. Premarket approval is a regulatory responsibility of the FDA, which may not be accomplished by private sector or other Government sources. The Premarket Approval Process will be supported by the FARM system, which, although it is still in development, will be designated a mission critical system.

A Year 2000-related system failure would have a substantial impact on FDA's ability to efficiently complete the Premarket Approval Process, as indicated in Figure 2-1. Although FARM is not scheduled to be released until the Year 2000, its alternatives are discussed in this document, should one of the following events occurs:

- **FARM is completed and released in 1999, ahead of schedule;**
- **FARM experiences a Y2K failure when it is released in the Year 2000.**

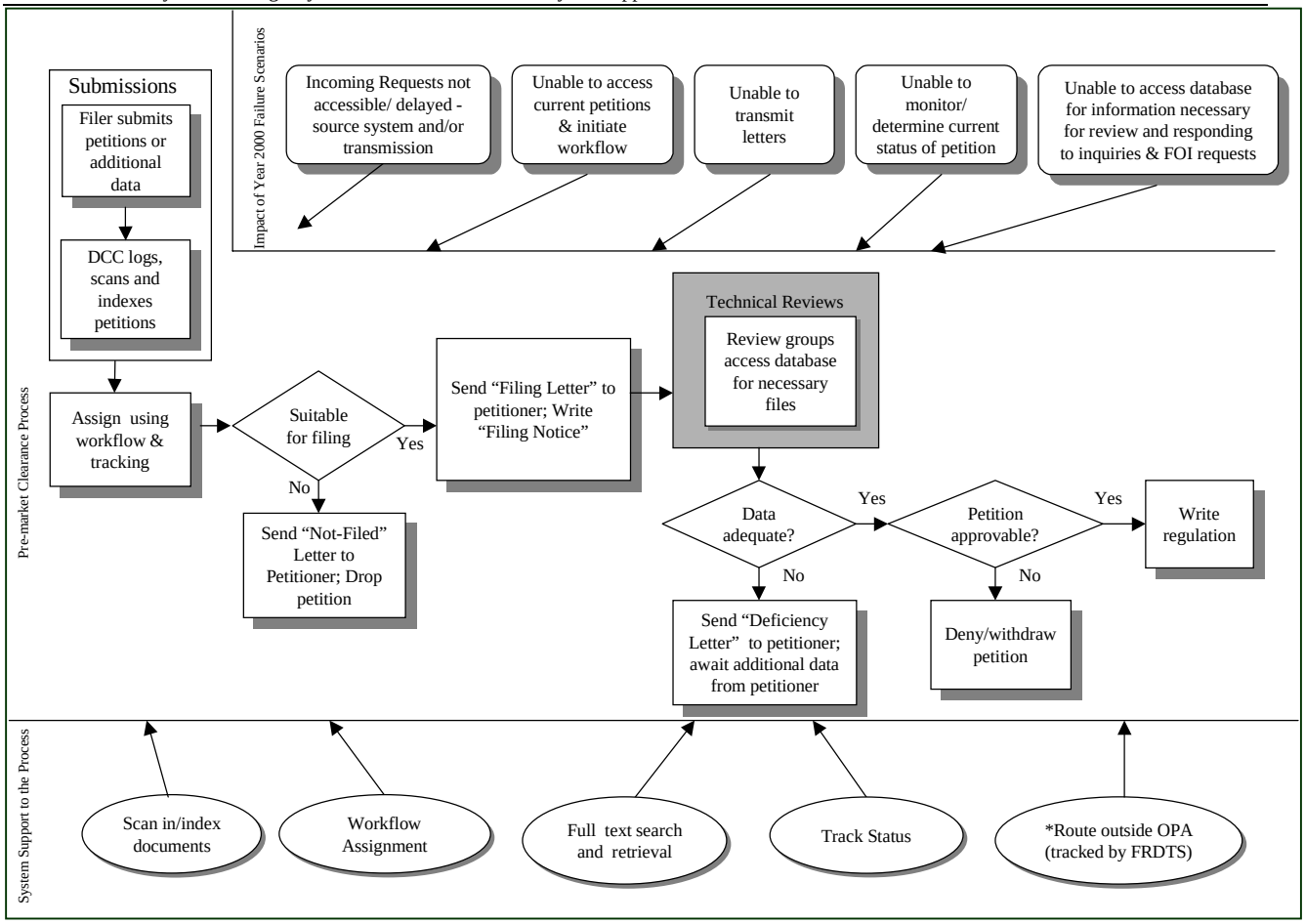

Figure 2-1. Premarket Approval Activities Business Process

2.1.2 Planning Roles and Responsibilities

Several information systems and functional staff are responsible for various aspects of the business continuity contingency planning effort. Duties include coordinating and developing recommendations on contingency actions, determining when contingency plans should be invoked, and deciding when it is safe to return to normal operations after the system has been restored. The CFSAN staff members listed in Table 2-1 are considered to be key personnel in this process.

Table 2-1. Planning Roles and Responsibilities

Name	Title	Role
Alan Rulis	Director, Office of Premarket Approval (202) 418-3100	Authorizes contingency plan implementation.
George Brindza	IRM Lead (202) 205-4233	Confirms whether a system failure is Year 2000-related. Works with Project Manager to determine the severity of the Y2K failure and appropriate actions to take.
JoAnn Ziyad	Project Manager, Functional Lead (202) 418-3116	Approves contingency plan. Determines whether a system failure is Year 2000 related. Provides estimated date of system restoration. Notifies functional staff of any unanticipated failures. Notifies OPA Director as soon as possible if system failures are discovered. Implements contingency plan, in conjunction with OPA Director. Monitors actual service levels. Approves the return to normal operations.

*Note: Table data provided by Center personnel.

2.1.3 Risk and Business Impact

The Business Impact Analysis document identified several possible Y2K failure scenarios related to CFSAN's mission critical system. The document also described the impact each failure would have on the Center's ability to complete its core business process. This information is summarized in Table 2-2. Risk information in the figure has been updated to reflect the current status of FDA's overall Year 2000 Compliance Program.

Table 2-2. Risk and Impact Analysis of Premarket Approval Business Process

Impact on Business Process	**Severity Level**	**Risk of Year 2000 Failure Scenario**		
		FARM System Failure	**Technical Infrastructure**	**Public Infrastructure**
Incoming Requests not accessible/ delayed – source system and/or transmission	Low	Low	Low	Low
Unable to access current petitions & initiate workflow	Low	Low	Low	Low
Unable to access database for information necessary for review and responding to inquiries & FOI requests	Low	Low	Low	Low
Unable to monitor/determine current status of petitions	Low	Low	Low	Low
Unable to transmit letters	Low	Low	Low	Low

CFSAN could maintain minimum service levels in the event of a full or partial system failure, as evidenced by the service levels the Center currently maintains using manual operations. The CFSAN staff has indicated that the levels of service listed in Table 2-3 apply to CFSAN's overall mission and its goal to effectively serve the public.

Table 2-3. Premarket Approval Activity Service Levels

ACTIVITIES	**Current Service Levels**	**Minimum Service Levels**
Petitions Reviewed/year	60	50
Regulations Issued	40	35

*Note: Table data provided by Center personnel.

It is estimated that these reduced levels of service may be continued for 60 days before the level of work would demand restoration to full capability. All business continuity contingency plans must ensure that these mission critical requirements are addressed.

Because FARM is a new system development effort and will not be processing all active petitions by the Year 2000, current manual operations will continue to be performed on a subset of petitions not yet incorporated into FARM. Once FARM is successfully implemented, if there is a serious system failure and the problems

cannot be easily fixed, FARM will be shut down in an orderly manner. The users will then be directed to return to manual processes. This certainly is not desirable because the objective of FARM is to improve the productivity of the food and color additive petition review process, through the use of modern information technology.

These minimum acceptable service levels are dependent upon support from the technical and infrastructure.

The following infrastructure components are required for mission accomplishment:

- Telephones, faxes, and computers to transmit and access petitions, or fill FOI requests.
- Scanners, back-up drives, thesaurus, prepares tracking, routing, and signature forms.

2.1.4 Trigger Dates/Events

Several factors must be considered in implementing any contingency action. Full system failures may be directly related to problems with the software, hardware, or technical infrastructure. They may also result from an electrical power outage or some other public infrastructure failure. While full system failures are a concern, however, planners must also consider partial failures. While many experts predict that full system failures are likely to occur on or near January 1, 2000, partial failures may occur concurrently with, prior to, or after the century date change. In addition, it may not be immediately obvious that a partial failure has occurred. In such cases, the failure and the cause of the failure must be identified before system personnel can estimate restoration time.

Planners must consider the business impact in terms of the duration of a system failure. This impact must be considered in terms of the business process' execution cycle. For instance, if a particular business process operates on a six-month cycle, the impact of a 24-hour system outage may be negligible. This same 24-hour outage however, could have a severe impact on a business process that has a four-hour execution cycle. In addition to the duration of an outage, planners need to consider the severity of the failure. If, for example, printed reports display the year date incorrectly as "1900," and there has been no data corruption, FDA management may decide to report the problem to their IT staff without further action.

Trigger points have been identified for the business process supported by the FARM system. These triggers, which are based on dates and events when system failures may occur, may necessitate the implementation of the business process continuity plan. Stated differently, the trigger point determines when the functional staff must begin to work around the failure, in order to meet their minimum acceptable service level. The functional staff should always determine the severity of the failure and weigh that against the cost of implementing their contingency plan.

Table 2-4 identifies these trigger points and provides other important planning information. The first column lists the failure scenarios identified in the Business Impact Analysis. The second column indicates the date when the failure could occur (please note that this could be prior to January, 2000). The third column indicates how the failure will manifest itself to the functional team member. Finally, the fourth column provides guidance on when management should consider implementing the contingency plan.

Table 2-4. Trigger Points for Premarket Approval Business Process

Failure scenario	Projected date of first occurrence of failure	How failure will be recognized	Trigger point for implementing contingency plan
FARM System Fails	January 1, 2000	When the Center fails to review 4.16 petitions per month.	Seven days after detecting failure.
Technical Infrastructure Fails	January 1, 2000	Corrupted files. Unable to access FARM.	Seven days after detecting failure.
Public Infrastructure Fails	January 1, 2000	Loss of utilities, such as power, water, transportation, telecommunications.	Seven days after detecting failure.

*Note: Table data provided by Center personnel

2.1.5 Contingency Strategies

In this section of the document, various contingency actions are identified as responses to each of the failure scenarios shown in Table 2-4. Each of these failure scenarios will be addressed separately. Several alternative strategies were considered as possible responses to the failure scenarios. This section outlines the alternative strategies that were considered and provides the rationale for selecting the recommended alternative. It should be noted however, that the CFSAN staff has directed that a particular contingency strategy (manual) be used for all failure scenarios.

In developing the following contingency actions, then, planners should follow the following basic formula:

IF the failure scenario is still in effect **AT** the trigger date, **THEN** implement the contingency action.

OR

IF a failure will be corrected prior to the trigger date, **THEN** a contingency action is not needed.

2.1.5.1 FARM System Failure

According to GAO guidance, different alternatives were considered in planning for a system failure. A process could be done entirely manually, similar to the current petition review process. A second alternative is to develop a small system or tool set that would automate certain essential parts of the process. Finally, a third alternative would be to develop a complete back up to the system, which would fully automate the process. Naturally, any sort of automation developed as part of the contingency plan would need to undergo extensive Year 2000 testing.

Two alternatives were considered for the Premarket Approval Process. A manual work-around is discussed in Section 2.1.5.1.1, and a semi-automated alternative is discussed in Section 2.1.5.1.2. Because FARM is being

developed to be Year 2000 compliant, and will be validated through an Independent Validation and Verification process (IV&V), a fully automated back up was not considered.

2.1.5.1.1 Alternative 1 – "Manual"

To manually perform the Premarket Approval Process, the Document Control Clerk (DCC) must first receive and log in the submission. The DCC then prepares the petition to navigate the appropriate review channels. The petition is tracked using hard copies of files and indexes. The manual system is one that does not use any type of electronic or computerized tools.

2.1.5.1.2 Alternative 2 – "Semi-automated"

The semi-automated Premarket Approval Process is similar to the manual process, and is the process currently being used by CFSAN. The important difference is that instead of distributing and tracking work assignments and review documents in hard copy format, the managers will do so electronically. Also, using a semi-automated system, the DCC creates and indexes files electronically. The CSOs perform full text search and retrievals via the Oracle database.

2.1.5.2 Cost-Benefit Analysis of Alternatives

Because CFSAN has stated the manual alternative is the only viable option, the semi-automated alternative was not developed. The manual alternative costs are listed in Table 2-5.

Table 2-5. Cost Estimate for Manual Replacement Alternative

Resource	**Cost**
Incidental costs associated with shutting down FARM (once it is available) and reverting to manual operations	$5,000
TOTAL COST	$5,000

*Note: Table data provided by Center personnel.

2.1.5.2.1 Recommendation

The manual replacement is the recommended alternative. It is the only viable alternative because of the following attributes:

- Cost effectiveness
- Currently in use
- Least dependent on information technology, that is highly susceptible to Y2K problems
- Institutional knowledge exists among employees; therefore, implementation cost is minimal.

Table 2-6 is a suggested calendar for pre and post Y2K activities.

Table 2-6. BCCP Calendar for Premarket Approval Business Process

Date	Action	Responsibility
June 1999	Develop test procedures for Contingency Plan	Functional Lead - JoAnn Ziyad
June 1999	Test Contingency Plan and revise plan on basis of test results	Functional Lead -JoAnn Ziyad
October 1999	Advise CFSAN personnel that the document room will house emergency items for manual operations. Develop list of items for document room (forms, reports, lab reports, database printouts, etc.)	Director, OPA - Alan Rulis
October-December 1999	Stock document room with items and supplies	Administrative Support Staff
January-March 2000	Perform restoration (if FARM has been available for use when the outage occurred. It may not be, depending on when FARM development is complete).	Technical Support Staff

2.1.5.3 Technical Infrastructure Fails

The FARM application was developed and integrated by the Oracle Corporation. The back-end database engine is Oracle RDBMS. Several components such as Contact 2.0, Oracle's Transparent Gateway, Secure SQL Net, InterOffice 4.1, and Workflow comprise the remaining parts of the system. A Sun Microsystems Enterprise 3000 database server with dual processors running Solaris 2.5 hosts the FARM application. Input devices such as scanners and the user workstations complement the system. Currently, FARM resides in a

physically secure FDA location. Because of the sensitive information that this system retains, there is not a network connection to this system. Any data or information that must be obtained from FARM, as well as any development or maintenance of the application and data, must be performed on-site in the same physical space as the system. Network access from outside this area is being considered for future implementation. Consequently, FARM does not depend on a wide area network in support of the business operation.

2.1.5.3.1 Network

FARM does not use wide area network infrastructure components.

2.1.5.3.1 Desktop Computers

Desktop computers are connected through a local area network. All software is run off a local PC, instead of being located on the network server. Therefore, if the network is inoperable, the user can still perform work by using the various software programs on their desktop computer.

2.1.5.4 Public Infrastructure Fails

If CFSAN were to experience a failure in electricity, water, sewer, or telecommunications, its facilities would have to be closed, bringing the Center's work to a halt. The risk of any of these failures is low, however; therefore, this BCCP assumes that all necessary elements of the public infrastructure will be available.

In spite of the low risk, detailed planning has been accomplished for extended outages of public infrastructure elements, since failures in the public infrastructure could have devastating effects on CFSAN missions. The FDA Public Infrastructure Contingency Plan should be consulted in the event of a public infrastructure outage.

2.1.6 Resource Estimate

Table 2-7 provides a resource estimate for preparing for Y2K to the restoration phase. The figures provided are based on CFSAN personnel's assessment of their needs. Please note that this table only includes CFSAN's main office, in Washington, DC.

Table 2-7. Resource Requirements

Contingency Phase	Resources Required	Estimated Cost
Day One Preparation	Preparing extra forms Printing system screens and databases Acquiring stand-alone printers or cables to transform network printers into stand-alone Acquiring additional diskettes or CDs Etc.	0.2 FTE for 1 day 0.8 FTE for 1 day 0.2 FTE for 1 day Most personnel have stand-alone printers. $ 120.00 $ 50.00
Day One Operations	Personnel costs	3 FTE's for one day
Contingency Operations	Overtime for FDA personnel	1 FTE for the duration of contingency operations
Recovery Operations	Personnel costs to resolve backlog	2 FTE for every 2 days of contingency operations

Contingency Phase Definitions:

Day One Preparation – resources required and cost associated with preparing and putting in place all materials that would be necessary to operate under a Y2K contingency situation

Day One Operation -resources required (people only) and cost associated with assessing and reporting on status of automated systems on January 1, 2000.

Contingency Operations -resources required and cost associated with operating in the contingency mode under a Y2K failure condition

Recovery Operations -resources required and cost associated with returning to normal operations after a Y2K failure condition has been resolved

2.1.6.1 Recovery Actions

Restoration commences when FARM is restored to full functionality. The restoration process consists of the steps necessary for entering into FARM all reports and actions taken during the period when the manual replacement option was exercised. Table 2-8 describes the restoration actions.

Table 2-8. Restoration Actions for Premarket Approval

Step	Action	Lead Person
1	Identify all petition data that was completed or is in progress since the FARM outage.	Functional Lead
2	Collect and assemble hard copies of this data.	Administrative Support Staff
3	Prepare a schedule for entering petition data into FARM.	Functional Lead
4	Scan/keystroke in reports and data into FARM.	Administrative Support Staff
5	Perform a system check to ensure that the data is correctly entered into the FARM database.	Technical Support Staff

2.1.7 Plan Testing

The appropriate testing method for assessing the CFSAN contingency strategy for Premarket Approval Process is the development of desktop-level, manual contingency actions and the execution of a test of these manual actions. A complete description of the development and testing of contingency actions is provided in Appendix A-1.

2.1.8 Contingency Planning Sources

The following personnel were interviewed or otherwise participated in developing this draft document:

George Brindza –IRM Lead (202) 205-4233

JoAnn Ziyad – Functional Lead (202) 418-3116

Linda Lewis – Petition Control Assistant (Chemistry) (202) 418-3001

Sylvia Matson – Petition Control Assistant (EIS) (202) 418-3013

Judy Edwards – Petition Control Assistant (HEE) (202) 418-3051

Sylvia Dodson – Petition Control Assistant (Petition Control) (202) 418-3087

Freddy Felix – Document Control Center (202) 418-3118

Mark Causey – Indexing (202) 418-3394

Mitchell Cheeseman – Consumer Safety Officer (202) 418-3083

The following source materials were used in the development of this document:

- Memorandum from DHHS Chief Information Officer: “Year 2000 Business Continuity and Contingency Planning”.
- Year 2000 System Level Contingency Plans by Center (Pages 61-63) .
- Center’s Business case (Pages 1-16).
- FDA’s Strategic Year 2000 Business Continuity and Contingency Plan, Final Version dated August, 1998 (Reference 3.1.1, Foods, Page 12) The 1997 Annual Report.

3. CONTINGENCY ACTIONS FOR CFSAN BUSINESS PROCESS CONTINUITY

3.1 Introduction

In Section 2 of this document, Contingency Strategies for CFSAN Business Process Continuity, a manual mode of operation was identified as the strategic contingency for CFSAN's core business process. In this section, this strategy has been translated into specific manual procedures for each step of CFSAN's core business process. These manual procedures represent the contingency actions to be taken by CFSAN personnel to maintain business continuity in the face of a Y2K failure. Also included in this section are a Day One Preparation Checklist, which identifies those materials and elements needed to carry out the contingency actions and which must be in place before Day One (January 1, 2000), and a list of Actions and Backlog intended to assist CFSAN in returning to normal operation after the resolution of a Y2K problem.

This section contains two parts.

Section 3.1- Introduction: describes the approach taken in developing the contingency actions for CFSAN's core business process and provides guidance in using the material contained in the section;

Section 3.2 - Contains the contingency materials for the CFSAN Premarket Approval Process.

3.1.1 Objective

The objective of this section is to provide CFSAN the following tools to ensure core business process continuity:

A Day One Preparation Checklist;

- Specific Contingency Actions to be taken by CFSAN personnel to maintain core business continuity in the face of a Y2K failure; and
- A list of Backlog Resolution and Recovery actions.

3.1.2 Approach

The approach to the development of the contingency materials contained in this section included a refinement of the strategic material contained in Section 2 and the execution of a test program for each core business process to test and verify the contingency actions and materials developed.

For CFSAN's core business process, the high level, strategic process flow captured in Section 2 was refined to the step level through individual interviews and discussions with CFSAN process and subject matter experts. Individual process steps were analyzed for dependencies on personnel, mission critical systems, and technical infrastructure, and alternative manual contingency procedures were developed for each step. Also identified were the materials required for implementing the manual contingencies as well as ideas for backlog resolution. This material was reviewed in a group meeting with the CFSAN principals involved resulting in the selection of proper contingencies for each step and the verification of the overall process flow, the materials needed, and the approach to backlog resolution.

To test the contingency actions, a Test Plan was developed and a Test Case prepared for the core business process. The Test Case was intended to verify that business continuity could be maintained by implementing

the manual contingency procedures. The actual CFSAN personnel involved in the core business process participated in the testing at their desks. Prior to the test, a brief period of test training was conducted along with a Test Readiness Review to ensure all necessary materials were available. Following the test, a Test Report was prepared and any modifications to the manual procedures that became apparent during testing were captured. The Test Plan, Test Case, and Test Report for CFSAN's core business process is contained in the Appendices.

These tested manual procedures, Day One preparation materials, and backlog resolution actions are presented in this section as the tested and verified contingency actions and materials to be used by CFSAN should a Y2K problem arise.

3.1.3 When to Use This Chapter

The following process will be employed for initiating the contingency actions of manual operation should a Y2K induced system failure occur.

- Identify problem as Y2K system failure (see Tables 2-1 and 2-4 for failure identification criteria).
- Notify Program Manager - Functional Lead, Dr. JoAnn Ziyad, Code HFS-206, 202-418-3116.
- 24 hours, Functional Lead verifies the system failure.
- Corrective action to repair system failure is initiated.
- Within 48 hours, Functional Lead makes the decision to initiate the contingency plan.
- Functional Lead notifies the following departments/individuals that the process is going to manual operation:

    1. Office of the Director of Premarket Approval, Dr. Alan Rulis, Code HFS-200, 202-418-3100.
    2. Deputy Director of Premarket Approval, Dr. Laura Tarantino, Code HFS-200, 202-418-3104.
    3. Office of the Chief of Computer Systems Branch, George Brindza, HFS-676, 202-205-4233.

- Should the system remain unavailable for more than one work week, the following management team will convene to determine further contingency actions.

    4. Office of the Director of Premarket Approval, Dr. Alan Rulis, Code HFS-200, 202-418-3100.
    5. Deputy Director of Premarket Approval, Dr. Laura Tarantino, Code HFS-200, 202-418-3104.
    6. Office of the Chief of Computer Systems Branch, George Brindza, HFS-676, 202-205-4233.

- Once the system is restored, Functional Lead will make the decision to cease manual operation.
- Within 24 hours, Functional Lead notifies the following departments/individuals that the system has been restored:

    7. Office of the Director of Premarket Approval, Dr. Alan Rulis, Code HFS-200, 202-418-3100.
    8. Deputy Director of Premarket Approval, Dr. Laura Tarantino, Code HFS-200, 202-418-3104.

9. Office of the Chief of Computer Systems Branch, George Brindza, HFS-676, 202-205-4233.

10. Restoration and recovery actions will commence once the system has been restored to operational capacity.

11. Functional Lead will monitor that the recovery procedures are executed.

3.1.4 How to Use This Section

This section is intended to be used by CFSAN in preparing for Day One, executing contingencies if required, and recovering from a Y2K failure. Section 3.2, addresses CFSAN's core business processes, it contains a Day One Preparation Checklist, a set of Contingency Actions, and a list of Recovery Actions and Backlog Resolution. It is recommended that CFSAN use this information as follows:

Day One Preparation Checklist -	During the last calendar quarter of 1999, review this checklist to ensure all elements will be in place prior to January 1, 2000 and provide these elements to the CFSAN personnel who will need to use them should this plan be implemented.
Contingency Actions -	During the last calendar quarter of 1999, make copies of these pages of actions for the core business process and distribute to the organizations and individuals who will need to use them should this plan be implemented.
Recovery Actions and Backlog Resolution -	During the last calendar quarter of 1999, review these actions to ensure plans are in place to implement them should it be necessary.

3.2 Premarket Approval Process

The Premarket Approval Process is a mission critical process in which CFSAN accepts new food and color petitions and associated submissions for review and approval or other regulatory action. The following sections describe the CFSAN organizations supporting this process, the business process flow, the necessary "Day One" preparations and systematic operating procedures for executing the process manually should a Y2K failure occur.

3.2.1 CFSAN Organizations Involved in the Process

This process is supported by the following offices: Direct and Indirect Additives Branch in the Division of Petition Control (DPC), Scientific Support Branch and the Regulatory Policy Branch in the Division of Product Policy (DPP), the Division of Health Effects Evaluation (DHEE), and the Chemistry and Environmental Review Branches in the Division of Product Manufacture and Use (DPMU) Figure 3-1 graphically depicts the Center's organization and highlights the divisions directly involved in the process.

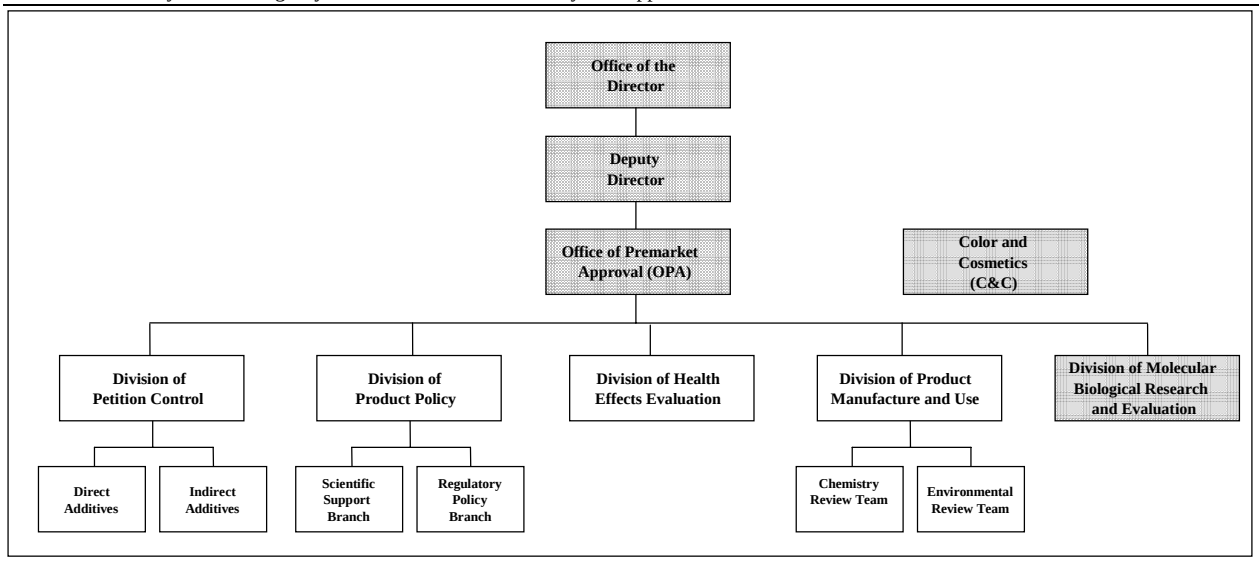

Figure 3-1. Organizations Involved in the Premarket Approval Process

3.2.2 Premarket Approval Process Flow

Figure 3-2 depicts the standard steps required for the review and approval of a New Petition, and supplemental submissions. The figure notes each point where an entry into the FARM database is required by the process and any critical sponsor interfaces such as Petition Receipt Notifications and Approval Notifications.

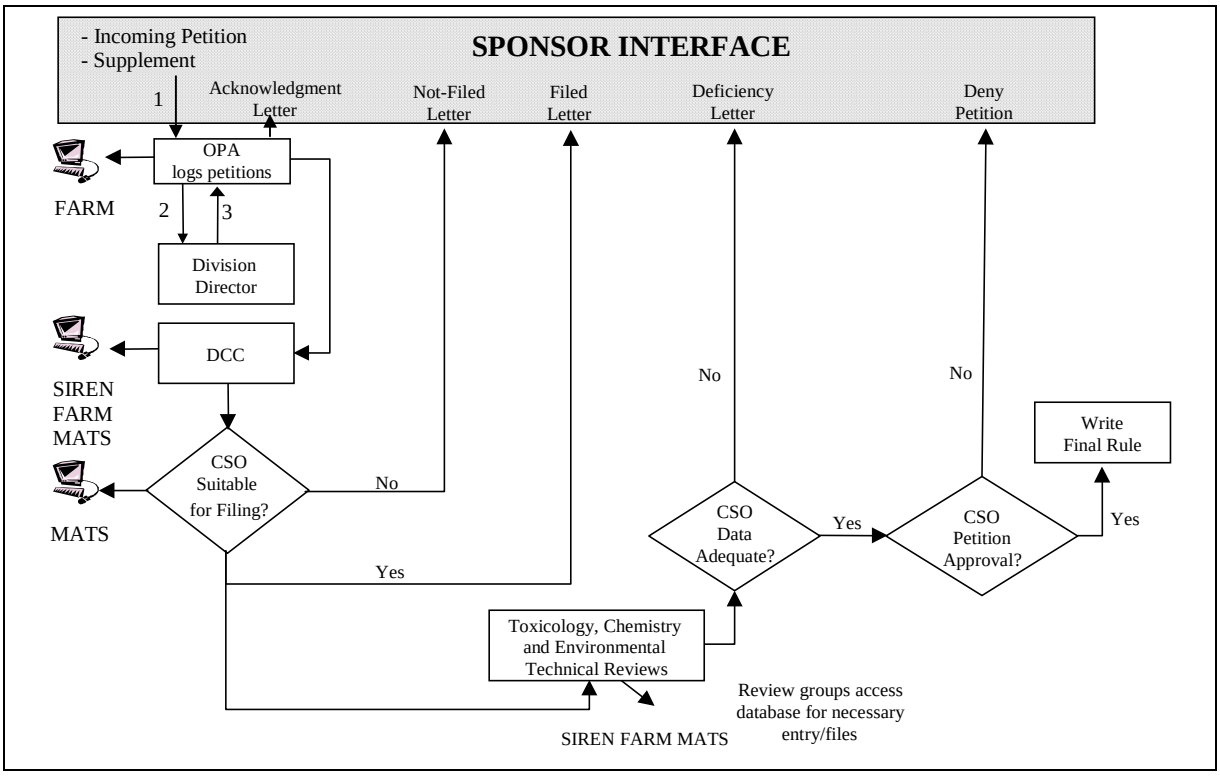

Figure 3-2. Premarket Approval Process Flow

3.2.3 Checklist for Day One Preparations

Day One Preparations are essential in the event that a Y2K failure occurs. These activities ensure that the Center has the necessary tracking forms and equipment, as well as trained personnel, for manual operations. Table 3-1lists Day One Preparations for each of the organizations involved in the Premarket Approval Process. This checklist should be reviewed and marked complete as each item is obtained.

Table 3-1. Office Premarket Approval Day One Preparations

Responsible Organization	Process Phase	Preparation Complete
DPC/DPP	1. Confirm that backup employees are cross-trained to perform function. 2. Confirm that manual date stamp allows 2000+ year. 3. Confirm that manual log is established to record filing status. 4. Confirm that word processing application has been downloaded onto harddrive. 5. Pre-print hard copy of the Listing of New Petition Log form and the Movement Log form. 6. Pre-print hard copy of the MATS manual log form. 7. Confirm that a field exists on the Movement Log form and the New Petition Log form to record the team assignment and the 15-day date. 8. Confirm that templates (Filed/Not-Filed letter and the Filing Notice letter) are created and saved to either diskette or hard drive. 9. Confirm that acknowledgement letter template is created and saved to either diskette or hard drive. 10. Confirm that local printer connection is operational. 11. Confirm FRDTS contact person and telephone number. 12. Confirm that diskettes will be available.	
DCC	1. Pre-print hard copy of the Siren Status/DCS update form. 2. Pre-print hard copy of the Power Level I form. 3. Pre-print hard copy of the MATS manual log form.	
DHEE	1. Confirm that backup employees are cross-trained to perform function. 2. Confirm that manual log is established to record backlog of all SIREN searches. 3. Confirm that word processing application is loaded on hard drive. 4. Confirm that local printer connection is operational. 5. Confirm that diskettes will be available. 6. Pre-print hard copy of the MATS manual log form.	

Responsible Organization	Process Phase	Preparation Complete
DPMU/Chemistry	1. Confirm that backup employees are cross-trained to perform function. 2. Confirm that a manual log is established for incoming/outgoing petition for review by the Chemistry Reviewers. 3. Confirm that a manual log is established to record petition assignment and petition status. 4. Confirm that word processing application is loaded on hard drive. 5. Confirm that local printer connection is operational. 6. Confirm that diskettes will be available. 7. Pre-print hard copy of the MATS manual log form.	
DPMU/ Environmental	1. Confirm that backup employees are cross-trained to perform function. 2. Confirm that logbook forms have been pre-printed. 3. Confirm that word processing application is loaded on hard drive. 4. Confirm that local printer connection is operational. 5. Confirm that diskettes will be available. 6. Pre-print hard copy of the MATS manual log form.	
IRM	1. Back up the FARM system every week in December 1999 to March 2000.	

3.2.4 Contingency Actions

3.2.4.1 Premarket Approval Process

Table 3-2 details the contingency actions required to complete the Premarket Approval Process. These actions serve as a step-by-step checklist for the users as they manually complete the process.

Table 3-2. Premarket Approval Process Contingency Procedures

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
1-1	DPC/DPP	Petition Control Assistant (PCA) opens new petition	❑ Yes ❑ No
1-2	DPC/DPP	PCA date stamp new petition with current date	❑ Yes ❑ No
1-3	DPC/DPP	PCA power on terminal	❑ Yes ❑ No
1-4	DPC/DPP	PCA locate the hard copy of the Listing of the Movement Log form and the New Petition form	❑ Yes ❑ No
1-5	DPC/DPP	On the Movement Log form, PCA hand write the originator, product, PCB number, subject, CSO name (if known), select direct/indirect, document item, date of move, orig. doc. Date, and date received	❑ Yes ❑ No
1-6	DPC/DPP	On the New Petition Log form, PCA hand write date received, and petition number	❑ Yes ❑ No
1-7	DPC/DPP	PCA route new petition to the Division Director to determine branch and team assignment	❑ Yes ❑ No
1-8	DPC/DPP	PCA record team assignment and 15-day date on the Movement Log form	❑ Yes ❑ No
1-9	DPC/DPP	PCA open word processing application on terminal from the hard drive	❑ Yes ❑ No
1-10	DPC/DPP	PCA insert floppy diskette with the acknowledgement letter template file into the disk drive	❑ Yes ❑ No
1-11	DPC/DPP	PCA open the acknowledgment letter template loaded on hard drive or on floppy disk	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
1-12	DPC/DPP	PCA print the acknowledgment letter on the designated stand-alone printer	❑ Yes ❑ No
1-13	DPC/DPP	PCA mail acknowledgment letter to the petitioner	❑ Yes ❑ No
1-14	DPC/DPP	PCA route the petition to the Document Control Center (DCC)	❑ Yes ❑ No
1-15	DCC	Locate hard copy of the DCC MATS Receiving Log/Portal form	❑ Yes ❑ No
1-16	DCC	Hand write the petition number, source, date, petitioned chemical, number of volumes, and comments	❑ Yes ❑ No
1-17	DCC	Locate hard copy of the Power Level 1 form	❑ Yes ❑ No
1-18	DCC	Hand write the document type, document number, date received, indexer, total volumes, total pages, chemical function, title, submitter, technical effects, food/product use, CAS number, and type (this form will be used to track petitions that will need to be scanned at a later date)	❑ Yes ❑ No
1-19	DCC	Hold Chemistry copy of the petition until the petition is filed **This process will continue at Step 1-36**	❑ Yes ❑ No
1-20	DCC	Hold Toxicology copy of the petition until the petition is filed **This process will continue at Step 1-37**	❑ Yes ❑ No
1-21	DCC	Route petition to the DPC/DPP Consumer Safety Officer (CSO).	❑ Yes ❑ No
1-22	DPC/DPP	CSO opens word processing application on terminal from hard drive	❑ Yes ❑ No
1-23	DPC/DPP	Insert floppy diskette with the filed/not-filed letter into disk drive	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
1-24	DPC/DPP	Modify and print the filed/not-filed letter as appropriate to the petition on the designated stand-alone printer	❑ Yes ❑ No
1-25	DPC/DPP	Route filed/not-filed letter to secretary for distribution and mailing	❑ Yes ❑ No
1-26	DPC/DPP	Secretary mail filed/not-filed letter to the petitioner	❑ Yes ❑ No
1-27	DPC/DPP	CSO insert floppy diskette with the Filing Notice into disk drive	❑ Yes ❑ No
1-28	DPC/DPP	Modify and print the Filing Notice as appropriate to the petition on the designated stand-alone printer	❑ Yes ❑ No
1-29	DPC/DPP	Route Filing Notice to Team Leader for review/approval	❑ Yes ❑ No
1-30	DPC/DPP	Mail (internally) the Filing Notice to the Regulations Editorial Staff (RES)	❑ Yes ❑ No
1-31	DPC/DPP	Locate and update the MATS manual log form	❑ Yes ❑ No
1-32	DPC/DPP	On the MATS manual log form for milestone 0, hand write the project, title, date received, L file, date due, status, CSO assigned to, deputy, office, division, branch, section, mail code, bldg., and phone	❑ Yes ❑ No
1-33	DPC/DPP	On the MATS manual log form for milestone 1.1.3 (draft filing notice), hand write project, petition number, date received, L file, status, date done, and CSO assigned to	❑ Yes ❑ No
1-34	DPC/DPP	Route petition to the Environmental Review Team **This process will continue at Step 4-1**	❑ Yes ❑ No

1-35	DPC/DPP	Inform DCC that petition has been filed **This process will continue at Step 1-38**	❑ Yes ❑ No
1-36	DCC	Route the petition to the Chemistry Review Team **This process will continue at Step 2-1**	❑ Yes ❑ No
1-37	DCC	Route the petition to the Division of Health Effects Evaluation (DHEE) **This process will continue at Step 3-1**	❑ Yes ❑ No
1-38	DPC/DPP	Secretary distributes copy of the filing letter to the PCA	❑ Yes ❑ No
1-39	DPC/DPP	PCA locates hard copy of the Movement log form	❑ Yes ❑ No
1-40	DPC/DPP	Hand write filing letter and date	❑ Yes ❑ No
1-41	DPC/DPP	Locate hard copy of the Siren Status/DCS Update form	❑ Yes ❑ No
1-42	DPC/DPP	Hand write the type of additive, the petition number, and status information	❑ Yes ❑ No
1-43	DPC/DPP	Route copy of the filing letter to DCC	❑ Yes ❑ No
1-44	DCC	File copy of the filing letter for scanning at a later date	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
2-1	DPMU Chemistry	Chemistry PCA locates the hard copy of the log book form	❑ Yes ❑ No
2-2	DPMU Chemistry	Hand write the date received, petition/subject, and company	❑ Yes ❑ No
2-3	DPMU Chemistry	Route petition to the Team Leader	❑ Yes ❑ No
2-4	DPMU Chemistry	Chemistry Team Leader assigns petition to Direct or Indirect Review Groups	❑ Yes ❑ No
2-5	DPMU Chemistry	Chemistry Group Leader Assigns petition to Chemistry Reviewers	❑ Yes ❑ No
2-6	DPMU Chemistry	Route petition assignment to the Chemistry PCA; routes petition to the assigned reviewer	❑ Yes ❑ No
2-7	DPMU Chemistry	Chemistry PCA locates hard copy of the logbook form	❑ Yes ❑ No
2-8	DPMU Chemistry	Hand write name of reviewer, and date assigned to	❑ Yes ❑ No
2-9	DPMU Chemistry	Chemistry Reviewer evaluates petition	❑ Yes ❑ No
2-10	DPMU Chemistry	Open word processing application on terminal from the hard drive	❑ Yes ❑ No
2-11	DPMU Chemistry	Begin drafting the review memo	❑ Yes ❑ No
2-12	DPMU Chemistry	Print the review memo on the designated stand-alone printer	❑ Yes ❑ No
2-13	DPMU Chemistry	Route the review memo to the Chemistry Group Leader	❑ Yes ❑ No
2-14	DPMU Chemistry	Chemistry Group Leader reviews/approves the review memo	❑ Yes ❑ No
2-15	DPMU Chemistry	Chemistry Reviewer locates and update the MATS manual log form	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
2-16	DPMU Chemistry	On the MATS manual log form for milestone 2, hand write the project, petition number, date received, L file, date done, status, CSO assigned to, deputy, office, division, mailcode, bldg., and phone	❑ Yes ❑ No
2-17	DPMU Chemistry	Route review memo and petition to the Chemistry PCA	❑ Yes ❑ No
2-18	DPMU Chemistry	Chemistry PCA locates the log book form	❑ Yes ❑ No
2-19	DPMU Chemistry	Hand write the section date and the final date	❑ Yes ❑ No
2-20	DPMU Chemistry	Route the review memo and the petition to the DPC/DPP PCA **This process will continue at Step 5-1**	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
3-1	DHEE	Technical Information Specialist (TIS) locates the hard copy of the Food Additives Petition Index form	❑ Yes ❑ No
3-2	DHEE	Hand write the regulation number, company, subject, application, and date received (this form will be used to track petitions that will need SIREN searches to be done at a later date)	❑ Yes ❑ No
3-3	DHEE	Route the petition to the Deputy Director	❑ Yes ❑ No
3-4	DHEE	Deputy Director assesses petition to determine if the petition warrants a regular review	❑ Yes ❑ No
3-5	DHEE	Deputy Director routes petition to Toxicology Reviewer	❑ Yes ❑ No
3-6	DHEE	Toxicology Reviewer evaluates petition	❑ Yes ❑ No
3-7	DHEE	Open word processing application on terminal from the hard drive	❑ Yes ❑ No
3-8	DHEE	Begin drafting the review memo	❑ Yes ❑ No
3-9	DHEE	Print the review memo on the designated stand-alone printer	❑ Yes ❑ No
3-10	DHEE	Route the review memo to the Toxicology Team Leader	❑ Yes ❑ No
3-11	DHEE	Toxicology Team Leader reviews/approves the review memo	❑ Yes ❑ No
3-12	DHEE	Reviewer locates and updates the MATS manual log form	❑ Yes ❑ No
3-13	DHEE	On the MATS manual log form for milestone 3, hand writes project, petition number, date received, L file, date done, status, CSO assigned to, deputy, office, division, mailcode, bldg., and phone	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
3-14	DHEE	Route review memo and petition to the Technical Information Specialist	❑ Yes ❑ No
3-15	DHEE	Toxicology Information Specialist locates the Food Additives Petition Index form	❑ Yes ❑ No
3-16	DHEE	Hand write petition assigned to, date of review memo	❑ Yes ❑ No
3-17	DHEE	Route the review memo (original and 2 additional copies) to the Portal System (DPC\DPP PCA) and the CSO (a third copy) **This process will continue at Step 5-1**	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
4-1	DPMU Environmental	Environmental Program Specialist (EPS) locates hard copy of the Environmental Review of Petitions log form	❑ Yes ❑ No
4-2	DPMU Environmental	Hand write date received, CSO and mail code, 180-day date, petition and subject, company, and date due	❑ Yes ❑ No
4-3	DPMU Environmental	Establish correspondence file	❑ Yes ❑ No
4-4	DPMU Environmental	Locate hard copy of the Petition Record Sheet	❑ Yes ❑ No
4-5	DPMU Environmental	Hand write MATS number, petition number, CSO, Petitioner, Chemical Identity, CAS number, proposed use, and date and action	❑ Yes ❑ No
4-6	DPMU Environmental	Locate hard copy of the Environmental Review Tracking form	❑ Yes ❑ No
4-7	DPMU Environmental	Hand write petition number, MATS number, milestone number, Received by Team, Due to Team Leader, petition 180-day date, due out, petitioner, CSO	❑ Yes ❑ No
4-8	DPMU Environmental	Route correspondence file and forms to the Team Leader	❑ Yes ❑ No
4-9	DPMU Environmental	Team Leader assigns petition to Environmental Reviewer	❑ Yes ❑ No
4-10	DPMU Environmental	Route petition assignment to the EPS	❑ Yes ❑ No
4-11	DPMU Environmental	EPS enters the petition assignment on the Environmental Review Tracking form and the Petition Record sheet	❑ Yes ❑ No
4-12	DPMU Environmental	Routes the petition to the assigned Environmental Reviewer	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
4-13	DPMU Environmental	Reviewer evaluates petition	❑ Yes ❑ No
4-14	DPMU Environmental	Open word processing application on terminal from the hard drive	❑ Yes ❑ No
4-15	DPMU Environmental	Begin drafting the Deficiency memo or Finding of No Significant Impact (FONSI) memo	❑ Yes ❑ No
4-16	DPMU Environmental	Print the Deficiency memo or FONSI memo on the designated stand-alone printer	❑ Yes ❑ No
4-17	DPMU Environmental	Route the Deficiency memo or FONSI memo to Environmental management	❑ Yes ❑ No
4-18	DPMU Environmental	Management reviews/approves the Deficiency memo or FONSI memo and routes memo to the Reviewer	❑ Yes ❑ No
4-19	DPMU Environmental	Reviewer redrafts or finalizes Deficiency or FONSI memo and routes memo and petition to the EPS	❑ Yes ❑ No
4-20	DPMU Environmental	EPS enters petition status on the Environmental Review Tracking form and the Petition Record Sheet	❑ Yes ❑ No
4-21	DPMU Environmental	Locate and update the MATS manual log form	❑ Yes ❑ No
4-22	DPMU Environmental	On the MATS manual log form for milestone 4, hand write the project, petition number, date received, L file, date done, status, CSO assigned to, deputy, office, division, mailcode, bldg., and phone	❑ Yes ❑ No
4-23	DPMU Environmental	Route Deficiency memo or FONSI memo to the PCA **This process will continue at Step 5-1**	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
5-1	DPC/DPP	PCA locates the Movement Log form	❑ Yes ❑ No
5-2	DPC/DPP	Enter the status of all three reviews on the Movement Log form	❑ Yes ❑ No
5-3	DPC/DPP	Hand write document item and date	❑ Yes ❑ No
5-4	DPC/DPP	Route review memos to the DCC	❑ Yes ❑ No
5-5	DCC	Route the review memos to the CSO	❑ Yes ❑ No
5-6	DPC/DPP	CSO opens word processing application on terminal from hard drive	❑ Yes ❑ No
5-7	DPC/DPP	Begin drafting the Final Rule	❑ Yes ❑ No
5-8	DPC/DPP	Locate the Document Tracking Slip	❑ Yes ❑ No
5-9	DPC/DPP	Hand write the short title, company name, title as it appears on the document, action, CSO name & mailcode, petition number, signature level, keywords	❑ Yes ❑ No
5-10	DPC/DPP	Route Document Tracking Slip to the PCA	❑ Yes ❑ No
5-11	DPC/DPP	PCA contacts the Office of Regulations Coordination's Staff at 202-205-4968 to obtain a FRDTS number	❑ Yes ❑ No
5-12	DPC/DPP	Route the FRDTS number to the CSO	❑ Yes ❑ No
5-13	DPC/DPP	CSO incorporates the FRDTS number into the processing form	❑ Yes ❑ No
5-14	DPC/DPP	Print the draft Final Rule on the designated stand-alone printer	❑ Yes ❑ No

STEP	RESPONSIBLE ORGANIZATION	USER ACTION	COMPLETED ACTION
5-15	DPC/DPP	Route copies of the draft Final Review to the Chemistry, Toxicology and Environmental Review Teams	❑ Yes ❑ No
5-16	Chemistry, Toxicology, and Environmental Review Teams	Evaluate the draft Final Rule and make modifications	❑ Yes ❑ No
5-17	Chemistry, Toxicology, and Environmental Review Teams	Route draft Final Rule to the DPC/DPP CSO	❑ Yes ❑ No
5-18	DPC/DPP	CSO opens word processing application on terminal from the hard drive	❑ Yes ❑ No
5-19	DPC/DPP	Begin making modifications to the Final Rule	❑ Yes ❑ No
5-20	DPC/DPP	Print the Final Rule on the designated stand-alone printer	❑ Yes ❑ No
5-21	DPC/DPP	Locate and update the MATS manual log form	❑ Yes ❑ No
5-22	DPC/DPP	Hand write the project, petition number, date received, L file, date done, status, CSO assigned to, deputy, office, division, mailcode, bldg., and phone	❑ Yes ❑ No
5-23	DPC/DPP	Route Final Rule to management for review/approval	❑ Yes ❑ No
5-24	DPC/DPP	Management routes the Final Rule to the CFSAN Director/Commissioner for approval	❑ Yes ❑ No

3.2.5 Recovery Actions and Backlog Resolution

Following a Y2K event, after the FARM System is restored to proper operation and tested, information that is affected will be entered into the FARM System by CFSAN personnel. Paragraph 2.1.6.1 identifies the actions lead personnel are to perform.

APPENDIX A - Contingency Test Materials for CFSAN Premarket Contingency

APPENDIX A - CONTINGENCY TEST MATERIALS FOR PREMARKET CONTINGENCY

The attached Appendix A contains the documentation used to complete the Premarket Contingency Plan testing phase. Included are the Test Plan, the Test Cases and the Test Report.

APPENDIX A- 1 Premarket Contingency Test Plan

APPENDIX A- 2 Premarket Contingency Test Cases

APPENDIX A- 3 Premarket Contingency Test Report